

That which is claimed is:

1. In a human subject in need of treatment with a therapeutic compound for an EGFR-expressing solid tumor, a method to assess whether the subject is likely to exhibit a favorable clinical response to said treatment, comprising:

- (a) determining the pre-treatment level of pERK in said tumor;
- (b) administering a therapeutically effective amount of an agent selected from an EGFR inhibitor, an erbB2 inhibitor, and a dual EGFR/erbB2 inhibitor; and
- (c) determining the level of pERK in said tumor after an initial period of treatment with said therapeutic agent,

where a decrease in the pERK level indicates said subject is more likely to exhibit a favorable clinical response to treatment with said therapeutic agent, compared to a subject with no change or an increase in pERK levels.

2. A method according to claim 1 where said initial period of treatment is the time required to achieve a steady-state plasma concentration of said therapeutic compound.

3. A method according to claim 1 where p-erk levels are assessed by immunohistochemical methods.

4. A method according to claim 1 where said p-erk levels are assessed by comparing the distribution of total erk between nucleus and cytoplasmic compartments of the tumor cell.

5. A method according to claim 1 where said tumor also expresses erbB2.

6. A method according to claim 1 where said tumor over-expresses EGFR or erbB2.

7. A method according to claim 1 where said solid tumor is an epithelial tumor.

8. A method according to claim 1 where said tumor is selected from breast, ovarian, colon, head and neck, bladder, renal cell and lung tumors.

9. A method according to claim 1 where said therapeutic agent is a dual EGFR/erbB2 inhibitor.

10. A method according to claim 1 where said therapeutic agent is GW572016.

11. A method according to claim 1 where said therapeutic agent is GW572016 and said initial treatment period is from about 14 days to about 28 days.

12. A method according to claim 1, further comprising determining the level of pAKT in said tumor pre-treatment and after the initial period of treatment.

13. A method according to claim 1, further comprising determining the level of cyclin D1 in said tumor pre-treatment and after the initial period of treatment.

14. In a human subject in need of treatment with a therapeutic compound for an erbB2-expressing solid tumor, a method to assess whether the subject is likely to exhibit a favorable clinical response to said treatment, comprising:

- (a) determining the pre-treatment level of pERK in said tumor;
- (b) administering a therapeutically effective amount of an agent selected from an EGFR inhibitor, an erbB2 inhibitor, and a dual EGFR/erbB2 inhibitor; and
- (c) determining the level of pERK in said tumor after an initial period of treatment with said therapeutic agent,

where a decrease in the pERK level indicates said subject is more likely to exhibit a favorable clinical response to treatment with said therapeutic agent, compared to a subject with no change or an increase in pERK levels.

15. A method according to claim 1 where said initial period of treatment is the time required to achieve a steady-state plasma concentration of said therapeutic compound.
16. A method according to claim 1 where p-erk levels are assessed by immunohistochemical methods.
17. A method according to claim 1 where said p-erk levels are assessed by comparing the distribution of total erk between nucleus and cytoplasmic compartments of the tumor cell.
18. A method according to claim 1 where said tumor also expresses EGFR.
19. A method according to claim 1 where said tumor over-expresses EGFR or erbB2.
20. A method according to claim 1 where said solid tumor is an epithelial tumor.
21. A method according to claim 1 where said tumor is selected from breast, ovarian, colon, head and neck, bladder, renal cell and lung tumors.
22. A method according to claim 1 where said therapeutic agent is a dual EGFR/erbB2 inhibitor.
23. A method according to claim 1 where said therapeutic agent is GW572016.
24. A method according to claim 1 where said therapeutic agent is GW572016 and said initial treatment period is from about 14 days to about 28 days.
25. A method according to claim 1, further comprising determining the level of pAKT in said tumor pre-treatment and after the initial period of treatment.

26. A method according to claim 1, further comprising determining the level of cyclin D1 in said tumor pre-treatment and after the initial period of treatment.